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K071361
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510(k) Summary

r4 Vascular Inc. Pegasus CT PICC

510(k) Summary of Safety and Effectiveness Information

Submitter Information

Submitter Name: r4 Vascular Inc.

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St. Paul, MN 55104

Telephone Number: (201) 394-2708

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Contact Person: Michael Sarajian

Date of Preparation: May 1, 2007

Device Name
Device Name: Pegasus CT PICC
Trade Name: Pegasus CT PICC
Common/Usual Name: Peripherally Inserted Central Catheter (PICC)
Classification Panel: General hospital
Classification Name: LJS - Long Term Intravascular Catheter
21 CFR 880.5970, Class II
Peripherally Inserted Central Catheter (PICC)

Predicate Device Name(s)
Device Name: Medcomp Pro-Line CT Power Injectable CVC Catheter
Trade Name: Medcomp Pro-Line CT Power Injectable CVC Catheter
Common/Usual Name: CVC Catheter
Classification Name: Long Term Intravascular Catheter (LJS)
Premarket Notification: K053345, concurrence date-December 20, 2005

Device Description

- The Pegasus CT PICC catheters are radiopaque polyurethane.
- Catheter usable length is 55 to 60 cm in length. It is available in a 4F/5F single lumen and 5F/6F dual lumen version.
- The catheter has a reverse taper design.
- Catheter lumen tubing is marked with depth markings for proper placement of the catheter during insertion.
- Catheters are provided sterile in basic radiology and nursing PICC configurations.
- The catheter has one power injectable lumen.
- Purple colorant was added to the catheter materials to distinguish it from other non-power injectable catheters and recognize it as a power injectable catheter.
- The catheter extension, ID rings are printed to identify the catheter as a Power Injectable Catheter to ensure proper use of the device.

Intended Use

The Pegasus CT PICC Catheters are intended for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling.

Indications for Use

The indications for use have not changed from the predicate Pro-Line Power Injectable catheter (K053345). The **Pegasus CT PICC** catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy and power injection of contrast media. For blood sampling, infusion or therapy, use a 4 French or larger catheter. The maximum recommended infusion rate is 5cc/sec. for power injection of contrast media for a 5F and 6F catheter. The maximum pressure of power injectors used with the 5F and 6F **Pegasus CT PICC** catheter may not exceed 300 psi. The maximum recommended infusion rate is 4cc/sec. for power injection of contrast media for a 4F catheter. The maximum pressure of power injectors used with the 4F **Pegasus CT PICC** catheter may not exceed 200 psi.

Characteristics of Proposed Device vs. Predicate Device

- The technological characteristics such as design and materials are identical to the predicate device.
- The analysis did not raise any new types of safety or effectiveness questions.

Listed below are the FDA guidance documents and international standards that were followed to measure the device's performance:

- ISO 10555-1.1997, Sterile, Single-Use Intravascular Catheters, General requirements,
- ISO 10555-3:1997, Sterile, Single-Use Intravascular Catheters, Central venous catheters
- AAMI/ANSI/ISO 11135:1994, Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization
- ISO 10993 Biological Evaluation of Medical Devices Part-I: Evaluation and Testing

All materials used in the manufacture of the proposed device were previously cleared for similar applications by predicate manufacturer per ISO 10993 requirements for a permanent contact device.

Verification and validation testing was performed in accordance with the protocols mentioned above per recommendations and standards, as well as in accordance with in-house protocols.

Clinical studies were not considered necessary since in vitro testing performed on the equivalent predicate device sufficiently demonstrated safety and effectiveness.

Conclusion

The r4 Vascular Inc. Pegasus CT PICC Power Injectable catheter is substantially equivalent to the predicate device in terms of intended use, insertion method, anatomical location, design, performance, labeling, manufacturing process and method of sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 20 2007

Michael Sarajian
Chief Executive Officer
R4 Vascular, Incorporated
1246 University Avenue West, Suite 438
Saint Paul, Minnesota 55104

Re: K071361
Trade/Device Name: Pegasus CT PICC
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: August 17, 2007
Received: August 17, 2007

Dear Mr. Sarajian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071361

INDICATIONS FOR USE

510(k) Number:

Device Name: PEGASUS CT PICC

Indications for use: THE R4 VASCULAR INC. PEGASUS CT PICC IS INDICATED FOR SHORT TERM AND LONG-TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY AND POWER INJECTION OF CONTRAST MEDIA. FOR BLOOD SAMPLING, INFUSION, OR THERAPIES, USE A 4F OR LARGER CATHETER. THE MAXIMUM PRESSURE OF INJECTORS USED WITH THE 5F AND 6F PEGASUS CT PICC CATHETER MAY NOT EXCEED 300PSI. MAXIMUM RECOMMENDED INFUSION RATE IS 5CC/SEC FOR 5F AND 6F CATHETER. THE MAXIMUM PRESSURE OF INJECTORS USED WITH THE 4F PEGASUS CT PICC CATHETER MAY NOT EXCEED 200PSI. MAXIMUM RECOMMENDED INFUSION RATE IS 4CC/SEC FOR A 4F CATHETER.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for ADW

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071361